

d.) Remarks.

Applicant has amended claim 1 to correct a typographical error as pointed out by the Examiner: the word “couple” should have read “coupled,” as it now does. Further, the term “comprising” has been deleted from independent claims 1, 14, 17, 31 and 39 when referring to the sequence itself and replaced with the phrase “consisting essentially of.” No new matter or new issues are raised with these amendments and their entry is respectfully requested. Currently claims 1-19 and 24-41 are pending.

Interview with Examiner and Supervisory Patent Examiner

The undersigned thanks Patent Examiner Yunsoo Kim and Supervisory Patent Examiner Christina Chan for the courtesy of an interview on May 17, 2007. During this interview, the undersigned, Examiner Kim and Supervisory Examiner Chan discussed the enablement rejection under 35 U.S.C. § 112, first paragraph. Supervisory Examiner Chan asserted that the scope of the claims, which is the first step in analyzing an enablement issue, was too broad because the claim recited the term “comprising” when referring to the sequence. The undersigned noted that the claims were not mere sequence claims, but contained other aspects to the invention including, a recitation that a plurality of fatty acids was also present. The undersigned noted that this and other recitations sufficiently limited the scope of the claims and as such is fully enabled. Supervisory Examiner Chan stated that limiting the sequence to a sequence “consisting of” a specific SEQ ID NO would render the claims allowable. The undersigned noted that SEQ ID NO 3 is the consensus sequence for the peptide and therefore “consisting” would improperly limit the invention. In addition, limited the claims to consisting of terminology would cause a problem for all subsequent claims which recited that one or more amino acids were added to the sequence. Supervisory Examiner Chan suggested stated that all such claims be made independent, which would necessarily include at least claims 1-3, 7-10, 12 and 34-36. The undersigned noted that, making all claims independent clearly shows that Applicant had enabled more than the one sequences and, thus, the phrase “consisting essentially of” should be appropriate. The undersigned further stated that reciting that the peptide consisted essentially of the sequence recited in the SEQ ID NOs would be acceptable to the Applicant for the purpose of obtaining an immediate allowance. Supervisory Examiner Chan asserted that the phrase may be

acceptable, but requested that the undersigned show support for this exact phrase in the specification. The undersigned asserted that support was clear from the sequence depicted in Figure 5. Supervisory Examiner Chan stated that she would like to see Applicant's remarks placed into the record.

Also discussed was the § 112, second paragraph, rejection for alleged indefiniteness. The undersigned explained that "effective" was a term of art, but that it could be deleted if Examiner Chan would allow the claim. The undersigned also discussed the term low, as recited in the claims, and explained how that term also was a term of art, although could be deleted to allow the claim. Examiner Chan agreed to reevaluate this rejection in consideration of any remarks Applicant's in a Response.

Remarks Regarding 35 U.S.C. § 112, First Paragraph

Claims 1-19 and 25-41 stand rejected, under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification. Applicant respectfully traverses this rejection.

According to the Examiner, the specification is enabling for an isolated peptide consisting of SEQ ID NOs: 1-3 or 5 (Office Action page 2), but not for "any" isolated peptide sequence comprising SEQ ID NOs 1, 2, 3 or 5. Applicant respectfully disagrees.

First, what is claimed is not *any* isolated peptide comprising SEQ ID NOs 1, 2, 3, or 5, but a peptide with a sequence that has as a consensus, SEQ ID NO 3 (e.g. see claim 1). SEQ ID NO 3 consists of 6 amino acids and is believed to be the consensus sequence of a small group of peptides, many of which are disclosed and their sequences provided in the specification. Further, the peptide also comprises a plurality of fatty acids and has a precise immunological function. Therefore, Applicant is not claiming "*any* isolated peptide," but an isolated peptide with three limiting and distinct features. One of those features is a specific and definite sequence that is fully and appropriately enabled.

Thus, the pending claims are described in the specification and enabled in full compliance with the Revised Interim Guidelines for the Examination of Patent Applications under 35 U.S.C. § 112, first paragraph (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001). As set forth in these guidelines, "an adequate written description of

the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention" (page 1105). On page 1106, the guidelines further state that:

*Factors to be considered in determining whether there is sufficient evidence of possession include... **partial structure, physical and/or chemical properties, functional characteristics** alone or coupled with a known or disclosed correlation between structure and function... Disclosure of any combination of such identifying characteristics that **distinguish the claimed invention** from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. (emphasis added).*

Applicant respectfully asserts that the sequence information provided is fully descriptive to those of ordinary skill in the art from a complete reading of the specification including the claims, and in full compliance with the guidelines. Claim one's SEQ ID NO:3 provides at least a partial structure of the invention; the fatty acids provide further physical and chemical properties; and the immunological increase is a distinguishing and novel functional characteristic. Thus, Applicant respectfully requests that this rejection be withdrawn.

During the Interview with the Examiners Kim and Chan, this rejection of the claims was recognized as centering only on the word "comprising" in the second line of claim 1 as previously presented, the concern being that there is a lack of enablement for an unlimited number of amino acids added onto SEQ ID NO 3. Supervisory Examiner Chan proposed substituting the phrase "consisting of." The undersigned proposed a compromise with the phrase "consisting essentially of" in place of the "comprising" term. Accordingly, and solely to expedite prosecution, Applicant has amended the independent claims to use the phrase "consisting essentially of."

As set for in the Manual of Patent Examining Procedures:

"The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." MPEP 2111.03, quoting *In re Herz*, 537 F.2d 549, 551-52 (CCPA 1976) (emphasis in original).

Because the basic and novel characteristics of the claimed invention are clearly disclosed in the claims and also in the specification, Applicant's claimed invention is fully enabled. Moreover, the specification discloses that one of ordinary skill in the art could modify the sequence by adding one or more amino acids. To that end, Applicant teaches that the sequence may contain 7, 8, 9 or more amino acids, all of which are described and enabled in the specification. Further, additional variations are enabled to those of ordinary skill in the art.

For example, SEQ ID NO 3 being the "core" to a number of potential variants is supported on page 12 of the specification under the heading "Peptide Sequencing by Edman Degradation." The second full paragraph of page 9 also sets out the variations that have been experimentally discovered, such as the presence of arginine at the amino terminus and phenylalanine at the carboxy terminus. In the same paragraph, the variability of X1 and X2 in SEQ ID NO 2 is also described, lending further support and enablement for the word "comprising" in the independent claims. In this vein, claim 13 includes all of the stated limitations, reached through the adding on of variations throughout the specification, and this claim achieves one embodiment that the Examiner herself has stated that she believes to be enabled. For all of these reasons, Applicant respectfully asserts that, as of the filing date of the application, making a peptide with any of these sequence variations recited in the claims is well-known to those skilled in the art. Accordingly, the enablement rejection is moot and/or overcome.

During the Interview, the Examiner and her Supervising Examiner, alleged that Applicant needed to show support in the specification for the phrase "consisting essentially of." Applicant respectfully disagrees.

First, sufficient support for this phrase is evident from Figure 5 which shows not only the peptide limited to the consensus sequence, but also variations that can exist in certain areas of the sequence. As is well established, support need not be literal. It is sufficient that Applicant disclose examples or otherwise that which constitutes the scope of the claims (MPEP 608.01(o)¹).

¹ M.P.E.P. 608.01(o) "While an applicant is not limited to the nomenclature used in the application as filed, he or she should make appropriate amendment of the specification whenever this nomenclature is departed from by amendment of the claims so as to have clear

Second, phrases such as comprising, consisting and consisting essentially of are transitional phrases. As the MPEP instructs, a “transitional” phrase used to limit the scope of a claim, and as such, support must exist for the substantive scope of the claim, and not for the actual phrasing. In other words, were actual verbal support of the transitional phrase required and sufficient, the fact that Applicant recites the word “comprising” throughout the specification would serve as support for the original language of the now rejected claims. While applicant does believe that this support exists, not just for the word “comprising,” but for the substantial scope of variations it allows within the confines of the other recited limitations of the present independent claims, Applicant has agreed to compromise to the inherent limitation of the phrase “consisting essentially of,” with traverse, and for purposes of expediting prosecution.

Thirdly, although the Examiner proposed to allow the claims with the transitional phrase consisting of, this drastic of a narrowing would be entirely prohibitive of the additions which the dependent claims proffer on the invention, additions which are all supported in the specification. “The transitional phrase ‘consisting of’ excludes any element, step, or ingredient not specified in the claim.” MPEP 2111.03, quoting *In re Gray*, 53 F.2d 520 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“consisting of” defined as “closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith.”). “A claim which depends from a claim which ‘consists of’ the recited elements or steps cannot add an element or step.” *Id.* Here, the Examiner would have Applicant place the limiting “consists of” immediately following the preamble of the claim and, in the process, preclude every one of its dependent claims. For example, the MPEP cites *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004), a case with similar components to those of the present invention, in explaining how the language in question provides the limits of scope.

In determining the scope of applicant's claims directed to “a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion consists of the nucleotide sequence from... to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence

support or antecedent basis in the specification for the new terms appearing in the claims.” (emphasis added).

of SEQ ID NO:1 has promoter activity,” the court stated that the use of “consists” in the body of the claims did not limit the open-ended “comprising” language of the claims (emphasis added)...

The court affirmed the Board’s interpretation that the transition phrase “consists” did not limit the claims to only the recited numbered nucleotide sequences of SEQ ID NO:1 and that “the transition language ‘comprising’ allowed the claims to cover the entire involucrin gene plus other portions of the plasmid, as long as the gene contained the specified portions of SEQ ID NO:1 recited by the claim[s].”

By allowing the open-ended “comprising” in the preamble of the claim, supported variations would not be precluded in dependent claims. However, the claim is not limitless because of the additional strict limitations, including function, recited within the same claim. Similarly, in the present application, the function of increasing the effective innate immune system response of a patient is a strict limitation to which all dependent claims must comply. Moreover, by compromising with the phrase “consisting essentially of,” an even narrower scope is etched out by prohibiting the presence of any characteristics which would materially affect this recited function. This claim construction, therefore, sets forth an extremely limited scope for the claimed invention.

The limited scope of consisting essential of has been upheld in countless cases, including in the seminal *PPG Industries v. Guardian Industries Corp.*, where the Federal Circuit Court of Appeals held that Guardian’s product did not *significantly* affect the properties of PPG’s patent claims and therefore did not infringe. This outcome was the result of a narrow view of the effect of the phrase “consisting essentially of,” which should serve to ease the Examiner’s concern that Applicant is seeking too broad a coverage.

For at least the reasons outlined above, Applicant respectfully requests that this rejection be withdrawn.

Remarks Regarding 35 U.S.C. § 112, Second Paragraph

Claims 1-19 and 25-41 stand rejected, under 35 U.S.C. § 112 second paragraph, as allegedly indefinite because of the terms “effective” in claim 1 and the phrase “low toxicity and a low incidence” in claim 28. Applicant respectfully traverses this rejection.

The terms in question are not relative or undefined, and a person of ordinary skill in the art would be reasonably apprised of the metes and bounds of the present invention. The term “effective” is not only a precise term of art, but it is also defined in the last full paragraph of page 10 of the specification: “The effective amount of the isolated peptides is that amount sufficient to produce an effective serum concentration for treating or preventing the specific disease or disorder.

The terms “low toxicity” and “low incidence” are similarly terms of art, clearly understood and defined to those of ordinary skill in the art. What’s more, these terms are also supported by and defined in the specification at page 9: “ICPF demonstrates a surprisingly low toxicity and low incidence of untoward reactions and side effects after administration of a dose several times the therapeutic dosage.” Moreover, pages 26-27 under the heading of “Product Safety” provide toxicity and incidence results from endotoxin assays and protein translation tests.

For at least these reasons, Applicant respectfully requests that the rejection based on alleged indefiniteness be withdrawn. Nevertheless, should the Examiner otherwise allow the claims, Applicant would consider deleting the words effective and low.

Conclusion

In view of the foregoing amendments and/or remarks, reconsideration of the application and issuance of a Notice of Allowance is respectfully requested. If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner’s Amendment, the Examiner is respectfully requested to contact the undersigned at the number below.

Applicant believes no fee is due at this time. Should any fees be necessary in connection with the filing of this Responsive Amendment, the Commissioner is hereby authorized to charge Deposit Account No. 14-1437, referencing Attorney Docket No. 8109.005US, for any such fees; and Applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,
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